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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,906	07/14/2006	Luca Barella	4662-186	8721
23117	7590	11/18/2008	EXAMINER	
NIXON & VANDERHYE, PC			KIM, JENNIFER M	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22203			1617	
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,906	<b>Applicant(s)</b> BARELLA ET AL.
	<b>Examiner</b> JENNIFER M. KIM	<b>Art Unit</b> 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 July 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 10-13 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 10-13 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

The amendment filed July 29, 2008 have been received and entered into the application.

### **Action Summary**

The rejection of claims 10-13 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicants' amendment canceling the claims.

The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment canceling the claims.

The rejection of claims 1-5 under 35 U.S.C. 101 paragraph is hereby expressly withdrawn in view of Applicants' amendment canceling the claims.

The rejection of claims 6-9 under 35 U.S.C. 102(b) as being anticipated by Heininger (DE19939921A1, see translated copy) is hereby expressly withdrawn in view of Applicants' amendment canceling the claims.

The rejection of claims 10-13 under 35 U.S.C. 103(a) as being unpatentable over Kiso et al. (U.S.2003/0091614 A1) is being maintained for the reasons stated in the previous Office Action.

### **Response to Arguments**

Applicants' arguments filed July 29, 2008 have been fully considered but they are not persuasive. Applicants argue that claims 10-13 require a dosage range and schedule not described or reasonable suggested in the cited prior art. This is not found to be persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known that the vitamin E when combined with melatonin enhances the circadian rhythm normalization action of melatonin in view of Kiso et al. Kiso et al. also teach that effective amount range of vitamin E expressed in its effective amounts in percentages. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the amounts of the vitamin E expressed in percentages in the Kiso et al's teaching because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Further, no unobviousness is seen in the dosing schedule claimed because once the usefulness of a combination is known to treat a condition, it is within the skill of the artisan to determine the optimum dosing schedule that is convenient and appropriate for the each

of the individual medical patients being treated. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

#### **Claim Rejections - 35 USC § 103**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiso et al. (U.S.2003/0091614 A1).

Kiso et al. illustrates on their Fig 7, the administration of 0.005%  $\alpha$ -tocopherol (vitamin E) enhanced effect on the circadian rhythm normalization action of melatonin. (Example 3 and Fig. 7). Kiso et al. teach that melatonin is known for a factor involved in the regulation of the circadian rhythm. ([0009]. Kiso et al. teach that the circadian rhythm is attributed by long distance jet flights (jet lag), irregular lives due to work shifts, and desynchronosis syndrome (time zone fatigue). ([0003].

Kiso et al. do not teach the effective amounts of melatonin and vitamin E set forth in claims 13 and 10, dosing schedule set forth in claim 11, and melatonin and vitamin E in a combination to synchronize the circadian rhythm.

It would have been obvious to one of ordinary skill in the art to modify the teaching of Kiso et al. employ combination of  $\alpha$ -tocopherol and melatonin in the single formulation for the synchronization of circadian rhythm to treat the circumstances that desynchronize the circadian rhythm because Kiso et al. teach that  $\alpha$ -tocopherol

enhances circadian rhythm normalization action of melatonin and the combination is effective as shown by their example and because long distance jet flight such as jet lags are result from the desynchronization of circadian rhythm. One would have been motivated to make such a modification in order to achieve an expected enhanced benefit of normalizing circadian rhythm effectively to avoid various diseases and circumstances due to disturbance of the circadian rhythm such as jet lag. The amounts of active agents to be used, the dosing schedules are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/  
Primary Examiner, Art Unit 1617

Jmk  
November 17, 2008